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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/513,961

12/20/2004

Michael R Boyd

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45733 7590 05/07/2008

LEYDIG, VOIT & MAYER, LTD.  
TWO PRUDENTIAL PLAZA, SUITE 4900  
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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

05/07/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/513,961	<b>Applicant(s)</b> BOYD ET AL.	
	<b>Examiner</b> Zachariah Lucas	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,5,8,9,12,13,16,19,21-23,27-29,33,34,37,39-51 and 64-77 is/are allowed.
- 6) ☒ Claim(s) 2,53-55 and 59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,8,9,12,13,16,19,21-23,27-29,33,34,37,39-51,53-55,59 and 64-77.

### **DETAILED ACTION**

1. Claims 1, 2, 4, 5, 8, 9, 12, 13, 16, 19, 21-23, 27-29, 33, 34, 37, 39-51, 53-55, 59, and 64-77 are pending in the application.
2. In the prior action, the Final Rejection mailed on January 31, 2008, claims 1-37, 39-55, 59, and 64-77 were pending and under consideration in the application.
3. In the Response of March 31, 2008, the Applicant amended claims 1, 2, 16, 19, 37, 43, 47, 53-55, 66, 71, and 77; and cancelled claims 3, 6, 7, 10, 11, 14, 15, 17, 18, 20, 24-26, 30-32, 35, 36, and 52.
4. In view of the restatement of the written description rejection below, the Finality of the prior action is withdrawn, and the action is made Non-Final.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Restated and Maintained)** Claims 1, 3-16, 18-37, 39-52, 55, 59, and 64-77 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected on the basis that there is inadequate written descriptive support for the claimed inventions to the extent that the claims read on antiviral variants and fragments of SEQ ID NO: 1, or the use thereof. The Applicant has amended the

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rejected claims such that they no longer read on such antiviral variants and fragments. The rejection is therefore withdrawn from these claims.

However, claims 2 and 54 have been amended to read on inventions drawn to proteins, or antibodies that bind proteins, isolated from *S. varium* which have antiviral activity and comprise SEQ ID NO: 1, an amino acid that is 90% or more identical or homologous to that sequence, or a fragment thereof.

Because the amended claims indicate that the composition may be a fragment of SEQ ID NO: 1 (or one of the proteins having the indicated identity or homology therewith), the rejection is restated as a rejection of these claims. In particular, while the application has shown that full-length proteins of SEQ ID NO: 1, and presumably the homologues thereto, may be isolated from the indicated cells, there is no such showing with respect to fragments of the proteins.

There are no teachings in the art or the application to indicate what fragments may be isolated from the indicated cells, or which of such fragments would have the requisite anti-viral activity. Claims 2 and 54 are therefore rejected as lacking adequate descriptive support for anti-viral fragments of SEQ ID NO: 1 (or the proteins showing 90% identity or homology thereto) that may be isolated from the indicated cells.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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8. **(Prior Rejection- Withdrawn)** Claims 52 and 55 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 6,183,961. Claim 52 has been cancelled, and claim 55 has been amended to require that the antibody binds to the amino acid of SEQ ID NO: 1. The rejection is therefore withdrawn.

9. **(Prior Rejection- Maintained)** Claims 52-55 and 59 were rejected under 35 U.S.C. 102(b) as being anticipated by Boyd (US 6,193,982) in light of Ziolkowska et al. (Acta Biochim Pol 53: 617-26). The rejection is withdrawn from cancelled claim 52. However, Applicant continues to traverse the rejection of the remaining claims on the basis that the antibodies of the prior art do not comprise all of the HIV gp120, but only portions thereof, and that the cyanovirin and the scytovirin proteins bind different portions thereof. This argument is not found persuasive for the reasons indicated in the prior action, i.e., while all of the gp120 protein is not included in the internal image of in the antibody, the portion that is included contains oligomannose-9, which binds to both types of anti-viral proteins. The rejection is therefore maintained for the reasons above, and the reasons of record.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In*

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*re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **(Prior Rejection- Maintained)** Claims 52-55 and 59 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,193,982 in light of Ziolkowska. The rejection is withdrawn from cancelled claim 52. The Applicant traverses the rejection of the remaining claims for the reasons indicated above with respect to the anticipation rejection. The argument is not found persuasive for the reasons indicated above, and of record, with respect to that rejection.

### ***Conclusion***

12. Claims 1, 4, 5, 8, 9, 12, 13, 16, 19, 21-23, 27-29, 33, 34, 37, 39-51, and 64-77 appear allowable over the prior art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/

Primary Examiner, Art Unit 1648